



# Louisiana

## Manipulation Under Anesthesia

**Policy #** 00313

**Original Effective Date:** 09/14/2011

**Current Effective Date:** 04/18/2018

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers spinal manipulation (and manipulation of other joints, e.g., hip joint, performed during the procedure) with the patient under anesthesia, spinal manipulation under joint anesthesia, and spinal manipulation after epidural anesthesia and corticosteroid injection for treatment of chronic spinal (cranial, cervical, thoracic, lumbar) pain and chronic sacroiliac and pelvic pain to be **investigational**.\*

Based on review of available data, the Company considers spinal manipulation and manipulation of other joints under anesthesia involving serial treatment sessions to be **investigational**.\*

Based on review of available data, the Company considers manipulation under anesthesia (MUA) involving multiple body joints for treatment of chronic pain to be **investigational**.\*

*Note: This policy does not address manipulation under anesthesia for fractures, completely dislocated joints, adhesive capsulitis (e.g., frozen shoulder), and/or fibrosis of a joint that may occur following total joint replacement.*

### **Background/Overview**

#### **MANIPULATION UNDER ANESTHESIA**

Manipulation is intended to break up fibrous and scar tissue to relieve pain and improve range of motion. Anesthesia or sedation is used to reduce pain, spasm, and reflex muscle guarding that may interfere with the delivery of therapies and to allow the therapist to break up joint and soft tissue adhesions with less force than would be required to overcome patient resistance or apprehension. MUA is generally performed with an anesthesiologist in attendance. MUA is an accepted treatment for isolated joint conditions, such as arthrofibrosis of the knee and adhesive capsulitis. It is also used to reduce fractures (eg, vertebral, long bones) and dislocations.

MUA has been proposed as a treatment modality for acute and chronic pain conditions, particularly of the spine, when standard care, including manipulation, and other conservative measures have failed. MUA of the spine has been used in various forms since the 1930s. Complications from general anesthesia and forceful long-lever, high-amplitude nonspecific manipulation procedures led to decreased use of the procedure in favor of other therapies. MUA was modified and revived in the 1990s. This revival has been attributed to increased interest in spinal manipulative therapy and the advent of safer, shorter-acting anesthesia agents used for conscious sedation.

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### **MUA Administration**

MUA of the spine is described as follows: after sedation, a series of mobilization, stretching, and traction procedures to the spine and lower extremities are performed and may include passive stretching of the gluteal and hamstring muscles with straight-leg raise, hip capsule stretching and mobilization, lumbosacral traction, and stretching of the lateral abdominal and paraspinal muscles. After the stretching and traction procedures, spinal manipulative therapy is delivered with high-velocity, short-amplitude thrust applied to a spinous process by hand, while the upper torso and lower extremities are stabilized. Spinal manipulative therapy may also be applied to the thoracolumbar or cervical area when necessary to address low back pain.

MUA takes 15 to 20 minutes, and after recovery from anesthesia, the patient is discharged with instructions to remain active and use heat or ice for short-term analgesic control. Some practitioners recommend performing the procedure on 3 or more consecutive days for best results. Care after MUA may include 4 to 8 weeks of active rehabilitation with manual therapy, including spinal manipulative therapy and other modalities. Manipulation has also been performed after injection of local anesthetic into lumbar zygapophyseal (facet) and/or sacroiliac joints under fluoroscopic guidance (manipulation under joint anesthesia/analgesia) and after epidural injection of corticosteroid and local anesthetic (manipulation postepidural injection). Spinal MUA has also been combined with other joint manipulation during multiple sessions. Together, these therapies may be referred to as medicine-assisted manipulation.

### **Food and Drug Administration (FDA) or Other Governmental Regulatory Approval**

Manipulative procedures are not subject to regulation by the FDA.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD).

### **Rationale/Source**

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial that includes clinically relevant measures of health outcomes. Randomized, placebo-controlled trials are considered particularly important when assessing treatment of low back pain, to control not only for the expected placebo effect but also for the variable natural history of low back and pelvic pain, which may resolve with conservative treatment alone.

### **MANIPULATION UNDER ANESTHESIA**

In a 2008 comprehensive review of the history of MUA or medicine-assisted manipulation and the published experimental literature, Dagenais et al noted that there is no research to confirm theories about a mechanism of action for these procedures and that the only randomized controlled trial identified was published in 1971 when the techniques for spinal manipulation differed from those used presently.

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### **Nonrandomized Comparative Studies**

No high-quality randomized controlled trials have been identified. A 2013 comprehensive review of the literature described studies by Kohlbeck et al (2005) and Palmieri and Smoyak (2002) as being the best evidence available for medicine-assisted manipulation and MUA of the spine. Kohlbeck et al reported on a nonrandomized comparative study that included 68 patients with chronic low back pain. All patients received an initial 4- to 6-week trial of spinal manipulation therapy, after which 42 patients received supplemental intervention with MUA and 26 continued with spinal manipulative therapy. Low back pain and disability measures favored the MUA group over the spinal manipulative therapy-only group at 3 months (adjusted mean difference on a 100-point scale, 4.4 points; 95% confidence interval [CI], -2.2 to 11.0). This difference attenuated at 1 year (adjusted mean difference, 0.3 points; 95% CI, -8.6 to 9.2). The relative odds of experiencing a 10-point improvement in pain and disability favored the MUA group at 3 months (odds ratio [OR], 4.1; 95% CI, 1.3 to 13.6) and at 1 year (OR=1.9; 95% CI, 0.6 to 6.5).

Palmieri and Smoyak evaluated the efficacy of self-reported questionnaires to study MUA in a convenience sample of 87 subjects from 2 ambulatory surgery centers and 2 chiropractic clinics. Thirty-eight patients with low back pain received MUA and 49 received traditional chiropractic treatment. A numeric pain scale and the Roland-Morris Disability Questionnaire were administered at baseline, after the procedure, and 4 weeks later. Average pain scale scores in the MUA group decreased by 50% and by 26% in the traditional treatment group; Roland-Morris Disability Questionnaire scores decreased by 51% and 38%, respectively. Although the authors concluded that the study supported the need for large-scale studies on MUA and that the assessments are easily administered and dependable, no large-scale studies comparing MUA with traditional chiropractic treatment have been identified.

### **Observational Studies**

In 2014, Peterson et al reported on a prospective study of 30 patients with chronic pain (17 low back, 13 neck) who underwent a single MUA session with follow-up at 2 and 4 weeks. The primary outcome measure was the Patient's Global Impression of Change. At 2 weeks, 52% of the patients reported clinically relevant improvement (better or much better), with 45.5% improved at 4 weeks. There was a statistically significant reduction in numeric rating scale scores at 4 weeks ( $p=0.01$ ), from a mean baseline score of 4.0 to 3.5 at 2 weeks post-MUA. Bournemouth Questionnaire scores improved from 24.17 to 20.38 at 2 weeks ( $p=0.008$ ) and to 19.45 at 4 weeks ( $p=0.001$ ). This study lacked a sham group to control for a potential placebo effect. Also, the clinical significance of improved numeric rating scale and Bournemouth Questionnaire scores is unclear.

In 1999, West et al reported on a series of 177 patients with pain arising from the cranial, cervical, thoracic, and lumbar spine, as well as the sacroiliac and pelvic regions who had failed conservative and surgical treatment. Patients underwent 3 sequential manipulations with intravenous sedation followed by 4 to 6 weeks of spinal manipulation and therapeutic modalities; all had 6 months of follow-up. On average, visual analog scale ratings improved by 62% in patients with cervical pain and by 60% in patients with lumbar pain. Dougherty et al (2004) retrospectively reviewed outcomes of 20 cervical and 60 lumbar radiculopathy patients who underwent spinal manipulation postepidural injection. After epidural injection of lidocaine

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(guided fluoroscopically or with computed tomography), methylprednisolone acetate flexion distraction mobilization and then high-velocity, low-amplitude spinal manipulation were delivered to the affected spinal regions. Outcome criteria were empirically defined as significant improvement, temporary improvement, or no change. Among lumbar spine patients, 22 (37%) noted significant improvement, 25 (42%) reported temporary improvement, and 13 (22%) no change. Among patients receiving cervical epidural injection, 10 (50%) had significant improvement, 6 (30%) had temporary relief, and 4 (20%) had no change.

The only study (1995) of manipulation under joint anesthesia or analgesia found had 4 subjects. Later, Michaelsen noted in a 2000 article that joint-related MUA should be viewed with “guarded optimism because its success is based solely on anecdotal experience.”

### SUMMARY OF EVIDENCE

For individuals who have chronic spinal, sacroiliac, or pelvic pain who receive MUA, the evidence includes case series and nonrandomized comparative studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Scientific evidence on spinal MUA, spinal manipulation with joint anesthesia, and spinal manipulation after epidural anesthesia and corticosteroid injection is very limited. No randomized controlled trials have been identified. Evidence on the efficacy of MUA over several sessions or for multiple joints is also lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

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### **Policy History**

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09/01/2011 Medical Policy Committee review

09/14/2011 Medical Policy Implementation Committee approval. New policy.

12/08/2011 Medical Policy Committee review

12/21/2011 Medical Policy Implementation Committee approval. Added disclaimer.

12/06/2012 Medical Policy Committee review

12/19/2012 Medical Policy Implementation Committee approval. No change to coverage.

12/12/2013 Medical Policy Committee review

12/18/2013 Medical Policy Implementation Committee approval. No change to coverage.

04/02/2015 Medical Policy Committee review

04/20/2015 Medical Policy Implementation Committee approval. No change to coverage.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed

04/07/2016 Medical Policy Committee review

04/20/2016 Medical Policy Implementation Committee approval. No change to coverage.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

04/06/2017 Medical Policy Committee review

04/19/2017 Medical Policy Implementation Committee approval. No change to coverage.

04/05/2018 Medical Policy Committee review

04/18/2018 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 4/2019

### **Coding**

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	00640, 22505, 23655, 24300, 27275
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

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